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3761

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,402

Applicant(s)

MIZUTANI ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8 and 10-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the species of minisheet of Figure 7D, the species of attachment of Figure 4D, the species of individual packaging of Figure 27 and the species of multiple packaging of Figure 23C in the reply filed on 6-8-05 is acknowledged.

2. Claims 6-7 and 9 are still withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6-8-05.

Applicant's remarks have been considered but claims 6 and 7 do not read on Figure 27B especially as now proposed in the substitute specification, e.g. the substitute specification proposes that the finger opening is at a right angle to the container opening which is not what is claimed in claim 7.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

For example:

Substitute Specification

4. The substitute specification filed 12-13-05 has not been entered because the marked up copy does not comply with 37 CFR 1.121, i.e. does not show all the changes made to the originally filed specification to arrive at the clean copy of the substitute specification. For example, the marked up copy does not show the changes made to the section and subsection titles. The preliminary amendment to the description of Figure 4 is not reflected in the substitute specification. Therefore the following action is based on the originally filed specification including the abstract and the preliminary amendments thereto.

Drawings

5. The drawings were received on 12-13-05. These drawings are approved. See however the following paragraph.

6. The drawings are objected to because the descriptive text in Figure 28 should be avoided. Figure 27B does not show the finger opening and the package 150 opening pointing in the same direction as described on page 50. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets

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may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Description

7. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the abstract, line 5.

8. The abstract of the disclosure is objected to because terminology which can be inferred, e.g. "The present invention relates to", and legal terminology, i.e. "comprises", should be avoided. Correction is required. See MPEP § 608.01(b).

9. The disclosure is objected to because of the following informalities: 1) As set forth in MPEP 608.01(o), the meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import. The use of a confusing variety of terms for the same thing should not be permitted. The claims refer to, e.g., an exterior container comprising a package. However, a confusing variety of terms appears to have been used to describe such claim terms, e.g. the exterior container has also been referred to as the "outer vessel" in the title. Each of the claimed features should be referred to consistently

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by a single term rather than a variety of terms. 2) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims are not commensurate in scope. See MPEP 608.01(d). 3) On page 18, line 8, "19a" should be after "opening" not "finger". 4) In Figure 13, what is 48? 50 in Figure 14? 70 in Figure 17? 5) How does the exterior container disinfect as set forth on page 28, lines 11-12? 6) On page 29, line 14, "12" should be --112-- and on line 15, after "film", --118-- should be inserted. 7) On page 30, lines 3 and 4, "131" should be --133--.

Appropriate correction is required.

Claim Objections

10. Claims 1-5, 8 and 10-22 are objected to because of the following informalities: In claims 2-5, and 12-15, line 1, "An" should be --The--.. Claims 8, 10-11, 16-17 and 20-21 are considered claims depending from other claims but the preambles thereof are inconsistent with the claims from which they depend. In claim 18, second to last line, "least6" should be --least 6--.. On the second to last line of claim 19, "treatement" should be --treatment--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

11. Claims 1-5, 8, 10-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 22, how many treatments is Applicant claiming at a minimum? One or two? Is the sterilization the treatment or in addition to the treatment set forth in the second to last subsection? For the reasons set forth *infra*, the claims are indefinite, vague and too broad, see *Ex parte Slob*, *infra*. Furthermore, in claims 5 and 14, a positive structural antecedent basis for “said back side sheet” should be set forth. Note also similar language in claim 15 and the dependency thereof.

Claim Language Interpretation

12. “Side area” in claims 5 and 14-15 is defined as set forth on page 8, lines 12-15 of the specification. It is noted that “the neighborhood of the peripheral edge” therein is considered relative absent description of specific dimensions. The terminology “bonded” in claims 4-5 and 10-17 refers to direct and indirect bonding. The terminology “unbonded” in claims 5 and 14-15 refers to direct unbonding. With respect to all the claims except claim 3, the claimed processing or treatment is not claimed as being performed at a particular time, i.e. the processing can take place any time from the beginning point of manufacture, e.g. up to time of use. Due to the lack of clarity discussed *supra*, claims 8, 10-11, 16-17 and 20-21 are considered to require at a minimum an exterior container comprising a package capable of the function on lines 1-2 of claims 8, 16-17 and 20-21. Due to the lack of clarity discussed *supra*, claim 22 is considered to require at least the treatment set forth on the last line, i.e. gas sterilization.

Claim Rejections - 35 USC § 112, 1st paragraph

13. Claims 1-5, 8 and 10-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in MPEP 2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written rejection. The language should focus on those factors reasons and evidence that lead the examiner to conclude the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

First, what is the claimed invention? As set forth in the independent claims 1, 18, 29 and 22, the invention is considered to comprise at least an interlabial pad. The interlabial pad is further claimed as being treated or processed to contain not more than a certain number of live microorganisms therein, due to the processing or treatment, at a point in time at least six months, i.e. at six months or longer, from the processing or treatment. See Claim Language Interpretation section supra. It is disclosed that such number is to be determined by testing. Therefore, the claims also define the invention by any tests used to determine the number of live organism rather than set forth the specific structure of the end product, i.e. the claims are test characteristic claims. The claims are also product by product claims, see discussion infra.

Second, since the physical characteristics, i.e. the number of live microorganism therein, of the labial pad must be determined, e.g., by a test used to measure such characteristic, the scope of the claims is enabled to the extent the test, i.e. the method and equipment or parameters thereof, measuring such characteristic is described or disclosed.

In the instant application, no test whatsoever, i.e. no method, no equipment, has been disclosed with regard to measurement of the claimed characteristic. Contrary to Applicant's remarks, the test described on page 49, line 12-page 52, fourth to last line, as best understood, is used to measure the number of live microorganism in 10g of pad, note page 49, lines 24-25 and compare to page 52, line 10, up to six months from processing or treating of the combination of the pad, an individual wrapping container, an exterior container and an overwrapping film not a test for the measurement of the number of live microorganism in a pad at least six months from processing or treatment of the pad alone, i.e. the claimed characteristic. Furthermore, even the description of the test which has been set forth is unclear. For example, page 4, lines 19-24 and the abstract describe the characteristic as a measurement with respect to manufacture while page 44, line 21-page 45, line 3, as well as the test on pages 49-52, describe the characteristic as a measurement with regard to the process or treatment. For another example, the disclosure of such test on pages 49-52 is unclear, i.e. page 51, lines 15-16 refer to "the above-described test" but no test is described thereabove. For a third example, page 51, lines 17-26 disclose preparing some test solution, exposing a piece of pad thereto and making some kind of observation and judgement but it is not disclosed when this happens with respect to the processing or treatment of the pad nor what is observed and judged. Similarly, page 51, last line-page 52, fourth to last line describes the testing of a certain weight of the pad but does not, e.g., describe how such weight

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relates to that of an entire pad, i.e. are the results of the test correlated in some manner? In other words, the tests used, especially with respect to measurement of the claimed physical characteristics, are not described or disclosed, i.e. enabled, and thus, the claims relying on such are not enabled.

Third, the claims set forth the physical characteristics desired of the pad alone rather than the specific composition of the pad in the end product. Therefore, relying on *Ex parte Slob*, 157 USPQ 172, such claims could cover any conceivable combination of materials whether presently existing or which might be discovered in the future and which would impart the desired characteristic, i.e. the claims are too broad and indefinite since purport to cover everything having the characteristics regardless of its composition (It should be noted that 35 USC 101 sets forth "Whoever invents or discovers any new and useful...composition of matter...may obtain a patent therefor...title, i.e. does not include compositions that have yet to be invented and discovered.)

For these reasons and evidence, the examiner concludes the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

14. Claims 1-5, 8 and 10-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth in MPEP 2163, the issue of a lack of adequate written

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description may arise even for an original claim when an aspect of the claimed invention has not described with sufficient particularity such that one skilled in the art would recognize that the Applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art to or known to one of ordinary skill in the art. Further, as set forth in *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, the lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As discussed in the preceding rejection, the tests which are essential or critical to the selection of the pad have not been disclosed, there is a lack of disclosure or claiming of any specific composition/structure of the pad, and the claims are too broad in that the claims cover any conceivable combination of structure/processes either presently existing or which may be discovered in the future and which may impart the desired characteristics. Therefore, the claimed invention as a whole is not adequately described because the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art to or known to one of ordinary skill in the art and the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. Therefore, one skilled in the art would recognize that the Applicant did not have possession of the claimed invention.

Claim Rejections - 35 USC § 102/103

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: .

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-4, 12-13, 18-19 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McFall et al, PCT '689.

See Claim Language Interpretation section supra, Figures 1-5 and 8-9, and page 5, lines 19-27, page 7, first full paragraph, page 7, last full paragraph and page 33, second full paragraph, i.e. the pad is 20, the wrapping container is 50, the permeable side sheet is 42, the back side sheet is 38 and the absorber is 44. The McFall reference teaches all the claimed features except for the range of microorganism, i.e. a test characteristic, as set forth in the last subsection of claims 1 and 18, and the second to last subsection of claims 19 and 22. However McFall does teach a processing for the suppression of the number of microorganisms sometime during and/or after the manufacture of the pad but prior to combination with the package 50, see page 29, second full paragraph. Therefore, it is the Examiner's first position that since McFall includes all the claimed structure, processing and capabilities and also expresses the desire for microorganism

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suppression, that there is reasonable factual basis to conclude that the structure of the McFall also inherently possesses the claimed test characteristic i.e. the claimed range of microorganism in the pad at least six months from processing or treatment thereof, when tested according to Applicant's test, as best understood, see discussion supra. In any case, note again that McFall also recognizes the same problem/solution, i.e. need for microorganism suppression, i.e. see portions of McFall cited supra. Therefore, the Examiner's second position, even if the McFall et al reference does not teach the exact range of live microorganism, the general conditions of the claim are disclosed thereby and it is not inventive, i.e. it would be obvious to one of ordinary skill in the art, to discover the optimum or workable ranges, i.e. Applicant's ranges, by routine experimentation, In re Aller, 105 USPQ 233 (CCPA 1955). Finally, the Examiner's third position, claims 1-5, 8 and 10-22 are product by process claims due to the language in the last sections of claims 1, 18 and 22, the second to last subsections of claims 19 and 22 and with respect to claims 2-3 also due the language therein. As set forth in MPEP 2113, even though product by process claims are limited by and defined by the process, determination of novelty and inventive step is based on the end product itself not on its method of production. If the product in the product by process claim is the same as or obvious from the product of the prior art, the claim is unpatentable even though the prior product was made by another process. As discussed supra, since the composition of the pad of the end product is unknown, at most, the end product of claims 1-3, is known to be a pad or/and container. Since such a product appears to be the same or similar to that of McFall et al, the claims are considered unpatentable.

17. Claims 5 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFall et al in view of Wierlacher PCT '096.

See discussion of claims *supra* and the Claim Language Interpretation section. Also, see, e.g., page 32, last full paragraph of McFall et al. Therefore, McFall et al teaches that the handling aid for attaching the pad directly to the body may be a loop but does not disclose the specifics thereof, i.e. a mini sheet with bonded and unbonded areas. However, see Wierlacher at, e.g., Figures and page 17, line 30-page 18, line 30 and page 20, lines 19-24. To substitute the loop handling aid for attaching the pad directly to the body of Weirlacher for that of McFall would be obvious, *In re Siebentritt*, 54 CCPA 1083 (two equivalents are interchangeable for their desired function, express suggestion of desirability of substitution not need to render such substitution obvious). In so doing the prior art combination teaches the structure claimed of the minisheet in the claims.

18. Claims 8, 10-11, 16-17 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFall in view of Brisebois et al.

The claims require an exterior container and the specifics thereof which container is capable of packaging at least two of the individual wrapping body systems, all the claims except for claim 21, or at least one such body, claim 21, see Claim Language Interpretation section *supra*. McFall does not teach such an exterior container. However, it is well known to package a plurality of individual wrapping body systems together in a cardboard box or other container for efficient consumer sale. See, for example, Brisebois et al at col. 1, lines 26-42. It is also well known that such boxes or other containers include a main body and lid or flap which lid or flap is continuous with the main body but bent towards and bonded to the main body to form the package, see, for example, Figures 1 and 2 of Brisebois. Therefore, to employ an exterior container having the structure claimed in claims 8, 10-11 and 16-17 capable of packaging at least

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two individual wrapping body systems as taught by McFall would have been obvious to one of ordinary skill in the art in view of the recognition that such a container is well known in combination with such systems for efficient consumer sales thereof and the desire of efficient consumer sales with respect to any system intended for sale such as that taught by McFall.

Response to Arguments

19. Applicant's remarks with regard to the matters of form have been considered but are either deemed moot in that they have not been raised or are deemed not persuasive for the reasons set forth supra. Applicant's remarks with regard to the 112 first paragraph rejections have been considered but are deemed not persuasive for the reasons set forth supra, i.e. the test and parameters measured by the cited paragraphs are not those claimed, e.g. those measured are on some 10g of pad up to six months from processing, not measurements of a pad at least six months. With regard to the remarks with respect to the prior art Applicant's remarks are deemed narrower than the claims, the prior art teachings and the rejections based thereon, i.e. no argument has not provided which shows that the McFall does not inherently include such organism ranges, which shows it would not be obvious to include such ranges or which shows that the end product of the claims and the McFall device are different. It is noted that the claims are not method claims, they are apparatus claims.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

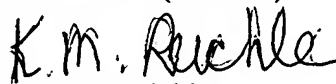
Any new grounds of rejection were necessitated by the amendments to the pending claims and the addition of new claims 18-22.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
March 16, 2006